UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

NEW ENGLAND CARPENTERS HEALTH AND WELFARE FUND, individually and on behalf of all others similarly situated,

Plaintiff,

v.

ABBOTT LABORATORIES,

Defendant.

Civil Action No.:_____

CLASS ACTION COMPLAINT
AND JURY DEMAND

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I. INTRODUCTION

1. Plaintiff New England Carpenters Health and Welfare Fund brings this proposed class action against defendant Abbott Laboratories for its unlawful prescription co-payment ("co-pay") subsidy programs. Defendant has paid, and continues to pay, undisclosed kickbacks to privately-insured individuals so that those health plan members choose defendant's branded drugs, AndroGel and Humira, instead of less-expensive therapeutic alternatives. Defendant knowingly caused health benefit providers to pay for more prescriptions of these drugs than they otherwise would have, and caused falsely-inflated drug reimbursement rates to be reported to, and imposed on, members' health benefit providers for these subsidized prescriptions.

2. Cost-sharing provisions in prescription drug benefit plans unite the financial interests of the health insurer with the interests of its beneficiaries. Requiring health plan members to pay a small portion of the high cost of a branded prescription drug — either a co-pay or co-insurance — provides a reasonable, personal incentive for privately-insured individuals to choose less-costly, usually generic, medications, and drives down the cost of the much larger residual portion paid by the health benefit providers.

3. In response to cost-sharing provisions, defendant began subsidizing members' co-payments for its key brand name prescription drugs. These subsidies are designed to undermine cost-sharing arrangements. By eliminating or reducing the member co-pays for branded drugs, plan members have no incentive to use less-expensive generic drugs, and health benefit providers end up paying for more costly branded drugs. A recent study estimated that these kickbacks will increase health benefit providers' prescription drug costs by *$32 billion* over the next ten years.

4. Each co-pay subsidy program is one size fits all, involving a formulaic, rote discountthat applies regardless of the details of the patient's cost-sharing arrangements. Presenting a co-pay subsidy card to a pharmacist triggers a secondary form of insurance —

provided by the manufacturer — that functionally reduces the price of the drug without disclosing that price reduction to the insurer. Each and every subsidy is calculated and processed electronically; the health benefit plans receive electronic records falsely indicating that the members paid their personal cost-share obligations, yet the manufacturer's digital paper trail discloses the truth — that the co-payments were subsidized by the manufacturer.

5. Carpenters and the proposed classes allege two bases for defendant's liability. First, federal racketeering law prohibits this form of insurance fraud. Through agreements with servicing companies, Abbott's routine waiver of co-payments means that the true costs for reimbursement of the routinely subsidized drug are less than represented by the drug manufacturer and pharmacy, and thus the amount of reimbursement imposed on the health benefit plan is inflated. The brand name defendant commits this fraud through its service providers, and the fraud is accomplished through the use of United States mail and wires. This suit seeks damages under 18 U.S.C. § 1964(c) for violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. §§ 1962(c) and (d).

6. Second, federal antitrust law prohibits this form of commercial bribery. Under Section 2(c) of the Robinson-Patman Act, a seller cannot lawfully pay undisclosed kickbacks to someone who makes a decision to purchase a product that is paid for by another. 15 U.S.C. § 13(c). Defendant subsidizes members' co-pays to induce them to purchase defendant's branded drugs instead of less-expensive therapeutic alternatives or AB-rated generic equivalents; health benefit providers then pay for the much more expensive branded drugs. Consumers who use defendant's co-pay savings cards or coupons are not told that their insurers are paying much more for defendant's brand-name drugs.

7. This suit seeks damages, on behalf of two classes of private health benefit providers, under Section 4 of the Clayton Act (15 U.S.C. § 15) for overpayments caused by defendant's undisclosed kickbacks.

II. PARTIES

8. Plaintiff New England Carpenters Health and Welfare Fund ("Carpenters") is a Massachusetts-based employee welfare benefit plan, established and maintained pursuant to §§ 1002(1) and (3) of ERISA, for the purpose of providing health benefits to approximately 22,000 eligible participants and beneficiaries located throughout New England. Carpenters is a jointly-administered Taft-Hartley fund, governed by a twenty-member Board of Trustees comprised of laborers and management representatives. Carpenters is part of a regional council of carpenters, the parent organization of all twenty-six local unions within New England. Carpenters' health benefits are funded through contributions from participants, including carpenters, millwrights, pile drivers and floor coverers, based on hours of work performed. During the course of defendant's subsidy schemes, Carpenters paid for much more expensive brand name drugs in circumstances where its members' cost-sharing obligations were not paid by them personally, but were subsidized by defendant. As a result of defendant's illegal subsidies, Carpenters purchased more of defendant''s expensive brand name drugs than it otherwise would have. Carpenters was injured as a result of defendant's unlawful conduct.

9. Defendant Abbott Laboratories ("Abbott") is a corporation organized and existing under the laws of the State of Illinois, with U.S. corporate headquarters at 100 Abbott Park Road, Abbott Park, Illinois. Abbott markets the branded drugs AndroGel and Humira. From in or around 2008 through the present, Abbott subsidized plan member co-pays in order to increase the number of AndroGel and Humira prescriptions purchased by health benefit providers.

10. OPUS Health, a division of Cegedim Relationship Management, is located at 1324 Motor Parkway, Suite 105, in Hauppauge, New York. OPUS Health administers a co-pay subsidy program for Humira, marketed by Abbott. OPUS Health acknowledges that the co-pay card is designed to overcome certain challenges faced by brand name manufacturers, including how to "speed adoption and build market share" and "influence [health care provider] script activity." A case study available on OPUS Health's website boasts of helping a pharmaceutical company develop a co-pay program that generated a 300% return on investment. OPUS Health is *not* named as a defendant in this action but is an unnamed co-conspirator.

11. TrialCard, Inc. is located at 6501 Weston Parkway, Suite 370, in Cary, North Carolina. TrialCard co-administers a co-pay subsidy program for AndroGel, marketed by Abbott. TrialCard advertises that it "provides branded Co-pay card programs that deliver an instant electronic rebate to a patient at the pharmacy, reducing out-of-pocket expense and equalizing tier position for [a manufacturer's] product." The company's website indicates that its co-pay program "[o]ffsets unfavorable tier/Co-pay position to level [the] playing field for patient out-of-pocket," and that one of its "client[s] reported [a return on investment] exceeding 600%." TrialCard is *not* named as a defendant in this action but is an unnamed co-conspirator.

12. Pharmacy Data Management, Inc. ("PDMI") is located at 1170 East Western Reserve Road in Poland, Ohio. PDMI co-administers a co-pay subsidy program for AndroGel, marketed by Abbott. On its website, PDMI claims that "[t]o date, [it has] been able to accommodate all copay requests, including multi-tiered benefits." PDMI is *not* named as a defendant in this action but is an unnamed co-conspirator.

III. STANDING

13. Carpenters has standing to bring this lawsuit for three independent reasons.

14. First, during the relevant time periods, and for each of the drugs and programs listed below, Carpenters paid for prescriptions in circumstances where the defendant's co-pay subsidy was not reflected in the overall reimbursement amount charged by the pharmacy and paid by Carpenters.

15. Second, during the relevant time periods, and for each of the drugs and programs listed below, Carpenters paid for prescriptions where the member's co-pay was subsidized by defendant.

16. Third, during the relevant time periods, and for each of the drugs and programs listed below, Carpenters paid for prescriptions that, but for defendant's co-pay subsidies, would have otherwise been written for and filled with less expensive medications.

IV. JURISDICTION AND VENUE

17. This action arises under section 4 of the federal RICO statute (18 U.S.C. §1964) and under section 2(c) of the Robinson Patman Act (15 U.S.C. §13), a 1936 amendment to the Clayton Act (15 U.S.C. §§ 12-27); the Court has subject matter jurisdiction under 28 U.S.C. § 1331 (federal question), 18 U.S.C. § 1964 (RICO), and 15 U.S.C. §15(a) (Robinson-Patman).

18. The activities of defendant Abbott were within the flow of, were intended to, and did have a substantial effect on interstate commerce of the United States. Venue, therefore, lies within this District under 28 U.S.C. § 1391.

19. Venue is also proper under the special venue provisions of the federal racketeering and antitrust laws, 18 U.S.C. § 1965 and 15 U.S.C. §22, as defendant Abbott is headquartered in this district and transact business within this District.

V. FACTS

A. Branded drug manufacturers have attacked the private prescription drug co-pay system.

20. Branded drug manufacturers have attacked the private prescription drug co-pay system by subsidizing plan members' co-pays in order to undermine cost-sharing arrangements between health benefit providers and those they insure. These co-pay subsidy programs reduce or eliminate individuals' co-pays regardless of their financial need.[1] Whether characterized as coupons, rebates, subsidies, or kickbacks, these payments to plan members interfere with health plans' cost-sharing provisions and intentionally influence prescription drug choices. The programs are designed, quite specifically, to reduce or eliminate privately-insured individuals' personal payment obligations so that they choose the brand name drugs and their health benefit providers foot the bill.

21. Although co-pay subsidy programs vary as to the drugs covered and the specific amount of the subsidy or rebate, all programs work the same way. Individuals enroll in drug-specific programs online.[2] Individuals provide basic information (name, address, and whether they have private health insurance coverage) and the drug company mails them a wallet-size card that includes instructions to pharmacists regarding how to process covered prescriptions. Some drug companies allow individuals to immediately print cards using their home computers.

22. Members then present their card at the pharmacy with a prescription, and the pharmacist processes the prescription according to the instructions on the card. The pharmacist enters information into a computerized data management system in order to submit a claim, first keying in the patient's health insurance information in the primary insurance field. Insurance

[1] Co-pay subsidy programs are, by definition, primarily or exclusively for privately insured individuals.

[2] In the infancy of these programs, drug companies gave co-pay subsidy cards to doctors and pharmacists, who in turn gave the cards to patients. Some cards are still distributed this way, but most are available online.

information regarding the transaction for that particular individual and his/her insurer is transmitted back to the pharmacist from the insurance company or its pharmacy benefit manager ("PBM"), including information about the member's co-pay or co-insurance obligation. The pharmacist then enters information from the co-pay card system into the secondary insurer field. Information regarding the extent of the co-pay subsidy or rebate is similarly computed, but only after the patient's primary insurance is processed (and billed).

23. The pharmacist and PBM use the reimbursement benchmark, which the brand name drug company provides to the reporting agency, to calculate the usual charge (*i.e.*, unreduced by the amount of the subsidy) to the health benefit insurer for the procurement of that prescription drug. The pharmacist and PBM do so without advising the insurer that, at the same time, the plan member's personal cost-share obligation is being picked up by the drug's manufacturer. As a result, the private health benefit provider pays for the medication at its usual (but in fact now inflated) cost, and it does so without being told that the usual cost-share obligation has not been paid by the enrollee, but rather by the brand manufacturer.

24. In effect, defendant bribes plan members to choose its branded drugs over less-expensive therapeutic alternatives in order to get the health benefit plan to pay for the bulk of the cost of its more expensive branded drugs. From the member's perspective, the branded drug and therapeutic alternatives cost close to, if not exactly, the same amount. But the price of the health benefit plan's share of the therapeutic alternative with the lower co-pay and the branded drug with the higher co-pay may differ by a factor of ten.

An Example: A brand drug company offers a co-pay card giving privately-insured individuals the opportunity to save up to $25 off their cost share for each prescription filled for a particular, and expensive, medication for chronic illness. The plan member brings the co-pay card to his pharmacy and provides his insurance card and co-pay card to the pharmacist. The pharmacist processes information from the insurance card and transmits it to the PBM. The PBM recognizes the drug as a TIER 3 brand drug for the plan member and relays a $70 obligation to the insurer and a $30 co-pay to the plan member.

In a separate transaction, the pharmacist processes information from the co-pay savings card or coupon. The co-pay card program administrator recognizes the $30 co-pay and covers $25 thereof, leaving $5 for the plan member to pay out-of-pocket (while the pharmacy charges the remaining $25 to the manufacturer through the co-pay card program administrator). The insurer is required to pay for the branded drug as if it were priced at $100, even though the usual cost for these subsidized transactions is $75, and even though there are equally appropriate, less expensive medications available at prices around 1/3 the cost of the branded drug.

25. By their terms, Abbott's co-pay subsidy programs (i) apply to individuals who are privately insured under a prescription drug plan that requires personal cost sharing by the member for retail prescription drugs such as those covered by the co-pay subsidy programs, (ii) undermine the contractual insurance arrangement between the insurer and the insurer's member by reducing or eliminating the personal cost-share feature of the insurance contract, (iii) causes the health benefit provider pay for more units of expensive co-pay subsidy drugs than it would have if the defendant had not interfered with the parties' performance of the contract, and (iv) increase the overall burden on the plan for providing benefits to its members.

26. Co-pay subsidy programs are also effectively a form of secondary insurance whereby defendant agrees to cover a portion of the privately-insured individual's prescription drug expenses. Prescription drug benefit plans, along with the formularies under which they operate, set forth appropriate balances in coverage terms, means of access, payment obligations and cost-sharing provisions for medications. Prescription drug insurance contracts — whether they are wholly private plans or plans that are privately-administered but publicly subsidized

(such as Medicare Part D plans or managed Medicaid drug plans) — are governed by myriad federal and state laws and regulations which ensure that the plans properly balance the availability of prescription drugs and sensible financial terms. Defendant's co-pay subsidies function as unregulated secondary health insurance that, after payment by the primary insurer, swoop in to relieve the plan member of specifically-designed *personal* financial obligations. By doing so, the co-pay subsidy programs fundamentally change the nature of the regulated relationship between health insurers and members. Although defendant's co-pay subsidies function as a form of secondary insurance, defendant does not comply with the myriad laws governing the provision of health insurance.

B. Cost sharing is critical to the effective functioning of health care in the United States.

27. In most economic systems, the person who *selects* the product or service is also the person who *pays* for the product or service. Health care is a big, notable exception. Typically, a physician or other health care provider (in consultation with the patient) *chooses* the medication or medical procedure, the patient *receives* the care or consumes the medication, and a public or private health benefit provider *pays* for the services and medication. The payer is separated from those who make the purchasing decision. Without cost-sharing provisions — such as percentage co-insurance or graduated co-pays — those choosing the prescription drugs (the patients in consulation with their physicians) have little or no incentive to choose less costly drugs.

28. Public and private health insurance relies on cost sharing to re-align the interests of patients, health care providers, and health benefit providers. Although cost-sharing techniques vary by type and amount, they all have the singular purpose of imposing a personal financial obligation on the covered individual in order to encourage price sensitivity and achieve the range

of acceptable balance between coverage and cost. Insured individuals often face point-of-service charges for medical services and prescription drugs. These include deductibles (amounts that must be paid before some or all services are covered), co-payments (fixed dollar amounts), and/or co-insurance (a percentage of the charge for services). Health benefit providers impose different degrees of cost sharing for different services: annual deductibles for medical services, a separate deductible for prescription drugs, hospital and outpatient co-insurance, co-pays for physician office visits, and/or out-of-pocket maximum amounts.

29. Cost sharing is therefore fundamental to almost all medical spending in the United States. Whether it be for hospital, physician, dental, or other health care provider services, for employer-sponsored or individual plans, for medical procedures, or for prescription drugs, numerous forms of cost sharing are imposed as a critical component of public and private health plans in order to carefully incentivize cost-conscious use of medical services and products while at the same time affording appropriate access to medical care.

C. The routine waiver of cost-sharing obligations, including co-payments and co-insurance, for medical services and products is unlawful.

30. Recognizing the ubiquity and necessity of cost sharing, federal and state statutes declare the practice of routinely waiving co-payment obligations for medical services and products to be unlawful.

31. First, routinely waiving co-pays constitutes financial inducements that are deemed illegal kickbacks. The waiver is in effect a form of payment that induces the use of medical services or products offered by the party that routinely waives co-pays. The routine waiver of co-pays amounts to health care fraud and is criminal.[3] In the public arena, physicians, hospitals,

[3] 18 U.S.C. § 1347: Health care fraud ("Whoever knowingly and willfully executes, or attempts to execute, a scheme or artifice to defraud any health care benefit program; or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program in connection with the delivery of or payment for health care benefits, items, or services, shall

and medical products providers who receive payment through Medicare or Medicaid programs and routinely waive co-payments or deductibles may be held in violation of federal and state anti-kickback statutes. The federal anti-kickback statute prohibits the payment of remuneration (any kickback, bribe or rebate) when it is knowingly paid to induce business that will be paid for by a federal health care program.[4] And the routine waiver of co-payments in the Medicare and Medicaid areas forms the basis for a violation of the False Claims Act and the Civil Monetary Penalties Law.[5]

32. Second, the routine waiver of co-payments constitutes a form of insurance fraud.[6] When cost sharing is routinely waived, the true acquisition cost for the medical service or product is not the stated or reported price being charged to health benefit providers, but rather the price *after deduction for the routinely waived co-payments*. The unlawfulness of this form of insurance fraud is well-known to physicians of any stripe, hospitals, and other health care providers. Physicians and other providers have been criminally prosecuted for routinely waiving co-payments yet still charging the insurer the inflated, pre-waiver price. The American Medical Association has long issued the following warning: "physicians should be aware that forgiveness or waiver of copayments may violate the policies of some insurers, both public and private. . . . Routine forgiveness or waiver of copayments may constitute fraud under state and federal law."[7]

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be fined under this title or imprisoned not more than 10 years, or both. . . . [A] person need not have actual knowledge of this section or specific intent to commit a violation of this section."); 18 U.S.C. § 1349: Attempt and conspiracy ("Any person who attempts or conspires to commit any offense under this chapter shall be subject to the same penalties as those prescribed for the offense . . . .").

[4] 42 U.S.C. § 1320a-7b(b).

[5] 42 U.S.C. § 1320a-7a; 31 U.S.C. § 3729.

[6] *See, e.g., Kennedy v. Connecticut Gen. Life Ins. Co.*, 924 F.2d 698, 699 (7th Cir. Ill. 1991) (appellant was required to collect co-payments from the insured patients if he wished to receive payment under an insurance plan that required co-payments: "Providers of medical care may seek to increase their business by promising to waive . . . co-payments. Patients prefer the lower outlays, but waivers annul the benefits of the co-payment system"); *id.* at 702 ("[a]llowing the provider to 'pay' the co-payment to himself is just another way to describe waiver of co-payments").

[7] American Medical Association Opinion 6.12, issued June 1993, *available at* http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion612.page.

33. Third, the terms of Abbott's co-pay subsodiy program would violate federal and state anti-kickback statutes. The federal anti-kickback statute (42 U.S.C. § 1320a-7b(b)(2)) provides:

> Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly . . . to any person to induce such person . . . to purchase . . . any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program . . . shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

34. The Massachusetts False Health Care Claims Act (MASS. GEN. LAWS ch. 175H, § 3) similarly provides:

> [A]ny person who offers or pays any remuneration, including any bribe or rebate, directly or indirectly . . . to induce any person to purchase . . . any good, facility, service, or item for which payment is or may be made in whole or in part by a health care insurer, shall be punished by a fine of not more than ten thousand dollars, or by imprisonment in a jail or house of correction for not more than two and one-half years or in the state prison for not more than five years, or by both such fine and imprisonment, and may be held liable in a civil action.

35. Defendant knowingly offers and pays remuneration in the form of co-pay subsidies to privately-insured plan members in order to induce the members to purchase defendant's brand name drugs. The federal government has acknowledged that co-pay subsidy programs may well violate the federal anti-kickback statute.[8]

36. Abbott knows that subsidizing a co=payment for a drug paid for by the federal government or a Massachusetts resident would violate these statutes. Although defendant's programs purport to exclude Medicaid and Medicare recipients and Massachusetts residents in

[8] *See* Publication of OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623, 70624 (Nov. 22, 2005) ("[W]e conclude that pharmaceutical manufacturer PAPs [Patient Assistance Programs] that subsidize Part D cost-sharing amounts present heightened risks under the antikickback statute.").

the fine print, on information and belief, the programs have been, and are being, used by persons who participate in those federal and state programs. For example, many individuals are enrolled in and receive prescription drugs under Medicare Part D; but because Medicare Part D benefits are sponsored by private health benefit providers, individuals enrolling in defendant's programs may report themselves as privately insured, *not* as Medicare patients. Similarly, many Medicaid patients receive their care through managed Medicaid programs run by private health insurers, not state agencies; again, when enrolling in defendant's co-pay subsidy programs, these individuals may report themselves as privately insured simply by clicking the appropriate "no" buttons on defendant's websites.

37. If Medicare's ban on co-pay coupons were not enforced, costs to the Part D program would increase by $18 billion over the period from 2012 to 2021.

38. Massachusetts is the only state that statutorily bans co-pay coupons for private payers. Were it to repeal that law, a recent study suggests that prescription drug costs for employers and other plan sponsors in Massachusetts would increase by $750 million by 2021. Many states that do not explicitly prohibit these programs will see similar — or even larger — increases. For example, Illinois plans are expected to spend nearly $1.4 billion extra on prescription drug costs as a result of co-pay coupons or programs during that time; Florida, New York, California and Texas will spend an extra $2 billion each in the next decade as a result of the same programs.[9]

[9] Visante, "How Copay Coupons Could Raise Prescription Drug Costs By $32 Billion Over the Next Decade", Nov. 2011, *available at* http://www.pcmanet.org/images/stories/uploads/2011/Nov2011/visante%20copay%20coupon%20study.pdf ("Visante Study"), at 13-15..

D. Health benefit providers use cost sharing to cope with ever-increasing prescription drug costs.

39. Cost sharing has particular importance in the coverage for prescription drug benefits. In 2000, prescription drug spending in the U.S. exceeded $142 billion. By 2009, spending ballooned to more than $300 billion. This increase in drug spending is in large part due to high and rising prices for the most well-known and most often used brand name drugs. In recent years, the price of the most widely used brand name drugs increased annually at approximately 6% to 9% — two or three times the general rate of inflation. Each of the drugs at issue in this action has seen significant price increases in recent years.

1. Public and private health benefit providers use tiered cost sharing to reduce spending on prescription drugs.

40. For both public and private health benefit providers, prescription drug cost sharing is widely and effectively used, and has been for many years.

41. In the public realm, beneficiaries under Medicaid have, for years, been required to pay a portion of the cost of their medications despite the fact that Medicaid eligibility is limited to low-income and disabled individuals. Similarly, even beneficiaries under Medicare Part B — generally the elderly receiving critical physician or in-home services — have been required to share the costs of their medications. And, more recently, beneficiaries under Medicare Part D are required to make co-payment or co-insurance payments under terms specified by Medicare Part D plan sponsors.

42. Most health insurance in the United States is provided by private health benefit providers. In the private realm, cost sharing for prescription drugs is similarly widespread. Under private health insurance plans, individuals and employers pay premiums to health benefit providers and, in turn, the health benefit providers agree to pay all or a portion of the cost of

needed medical services and products.[10] Well over 95% of covered employees in employer-sponsored private health benefit plans have prescription drug benefits. More often than not, the form of cost sharing is a co-payment rather than co-insurance, although co-insurance has steadily increased over time.

43. Drug benefit cost-sharing provisions have evolved over the decades, with the key innovation being the differentiation of co-payments among differing drugs. When drug insurance was first introduced, the plan member typically paid the same co-insurance (or co-pay) rate for any drug. Over time, that changed, and the price now depends on the "tier" in which the drug is placed. The early tiered plans typically had only two tiers, but most plans now have three or more tiers. In recent years, an increasing number of plans have created a fourth tier of drug cost sharing, which may be used for lifestyle drugs or expensive biologics:

Generic drugs: A drug product that is no longer covered by patent protection and thus may be produced and/or distributed by multiple drug companies.

Preferred drugs: Drugs included on a formulary or preferred drug list; for example, a brand name drug without a generic substitute.

Non-preferred drugs: Drugs not included on a formulary or preferred drug list; for example, a brand name drug with a generic substitute.

Fourth-tier drugs: New types of cost-sharing arrangements that typically build additional layers of higher co-payments or co-insurance for specifically identified types of drugs, such as lifestyle drugs or biologics.

Brand name drugs: Generally, a drug product that is covered by a patent and is thus manufactured and sold exclusively by one firm. Cross-licensing occasionally occurs, which allows an additional firm to market the drug. After the patent expires, multiple firms can produce the drug product, but the brand name or trademark remains with the original manufacturer's product.

[10] In the United States, most private health insurance is paid at least in part by employers, although it is also common for employees to contribute to the cost of their premiums. Truly individual health insurance policies may also be purchased.

44. The number of plans requiring some form of cost sharing that differentiates between forms of drugs has steadily increased, but has plateaued in recent years. Almost 90% of privately-insured individuals have some formula for tiered cost-sharing; over 75% are enrolled in plans with three, four, or more tiers of cost sharing for prescription drugs.

45. A drug's tier placement largely depends on its cost: Tier 1 drugs are less expensive, usually generic, drugs. More expensive, usually brand name, drugs are placed on higher tiers. Health benefit providers encourage members to choose Tier 1 drugs by imposing a lesser co-pay than that imposed for Tier 2 drugs. Tiered co-payments and co-insurance (which is a percentage of the overall cost of the drug at retail) thereby provide reasonable personal financial incentives to individuals to use equally effective, but less costly, medications. If a drug is placed on Tier 1, the member pays the pharmacy a relatively small co-payment. If the drug is placed on Tier 2, the co-payment or co-insurance obligation increases. The difference in the co-payment/coinsurance between Tier 2 and Tier 1 incentivizes the plan member to choose the less costly medication. If a drug is a Tier 3 drug, a therapeutic or generic equivalent will invariably exist for the medication in Tier 2 and/or Tier 1.

46. Another major, long-term trend has been the increasing *amount* of the co-payment or co-insurance required. Over the last decade, average retail co-payment levels increased by about 62%. Average co-payments for Tier 2 drugs increased by about 127%. Average co-payments for Tier 3 drugs increased the most, from about $17.53 in 1998 to about $42.95 in 2009, an increase of about 149%. As expected, the 2009 average retail co-payment for Tier 4 is even greater, at $62.11.

47. Widespread use of cost sharing for prescription drugs, the increasing trend of multi-tier cost sharing and the increasing amounts for co-payments and co-insurance are, of

course, no accident. Although other forms of prescription drug cost reductions may have more dramatic results — including the market entry of AB-rated generic equivalents — cost sharing has defined, measurable results. Cost sharing provides personal financial incentives to plan members to select the most cost-appropriate medications; these incentives work.

48. Patients — and to a lesser extent, their doctors — are sensitive to differences in co-payment requirements, particularly for maintenance drugs that they anticipate taking for long or indefinite periods of time. According to a 2007 literature review published in the Journal of the American Medical Association, *every 10% increase in cost sharing (through co-payments or co-insurance) reduces drug spending by 2 - 6%.* And drug companies are well aware that plan members consider co-pay differences when choosing prescription drugs: "[t]he patient, I will tell you, is economically very, very sensitive to co-pays, and a $5, $10, $20, $25 co-pay matters," says Abbott Laboratories Chief Executive Miles White.[11]

2. Branded drugs are expensive; differentiated cost sharing for branded and generic drugs helps health benefit providers and health plan members curtail prescription drug spending.

49. Generic drugs thus play a critical role in health benefit providers' attempts to curb ever-escalating prescription drug costs. Generic drugs are almost always significantly less expensive than their branded counterparts. On average, generic prescriptions cost payers $16, preferred brand prescriptions cost $118, and non-preferred brands cost $124. Tiered cost-sharing provisions thus incentivize generics by imposing a lower co-pay or co-insurance for generics than for brands.

50. AB-rated generics are, by definition, substitutable for their branded equivalents. All fifty states have laws that permit pharmacies to substitute AB-rated generics for their branded

[11] Event Brief of Q2 2009 Abbott Earnings Conference Call – Final, FD (Fair Disclosure) Wire (July 15, 2009).

counterparts when an AB-rated equivalent is available. Health benefit providers create strong incentives for plan members to demand generic drugs by imposing different co-pays for branded and generic drugs. Consequently, more than 90% of prescriptions for drugs that are available in both branded and generic forms are filled with a generic. 2010 IMS industry data — the industry's gold standard — reflects that, on average, AB-rated generics capture 80% of the brand's sales within the first six months.

51. In addition to AB-rated generics, a brand name drug may also have generic therapeutic alternatives. Therapeutic alternatives are *not* bioequivalent to their brand-name counterparts, but are alternative medicines that treat the same medical condition in a similar way. As an example, Pfizer's blockbuster drug Lipitor belongs to a therapeutic class of drugs called "statins" used to treat high cholesterol. But because statins work in similar ways, a patient and/or physician may determine that another statin, such as generic simvastatin, lovastatin, and pravastatin, is a sensible cost-effective alternatives — particularly since (without a co-pay subsidy) the cost to the patient by reason of the tiered co-payment system would be much higher for Lipitor than for a generic statin.

E. Co-pay subsidies work: health plan members fill prescriptions for branded drugs instead of generics and health benefit providers pay much higher prices for the subsidized prescriptions.

52. These kickbacks work. According to a 2011 study undertaken for the Pharmaceutical Care Management Association and based on evidence from drug coupon administrators, "25% of [co-pay] coupon use results in a couponed drug being used instead of a preferred brand or generic that might have been used in the absence of the coupon."[12] More than 100 million prescriptions were associated with co-pay coupons in 2010, accounting for 11% of

[12] Visantewww.pcmanet.org/images/stories/uploads/2011/Nov2011/visante%20copay%20coupon%20study.pdf Study at 11.

brand prescriptions.[13] These numbers will grow exponentially: At current trends, the number of prescriptions associated with co-pay subsidy programs will increase by 15% per year, reaching 500 million prescriptions and approximately 50% of non-specialty brand prescriptions by 2021.[14] All told, employers and other plan sponsors will likely spend an extra $32 billion on prescription drugs as a result of these co-pay subsidy programs over the next decade.[15]

53. It is estimated that pharmaceutical companies spend $4 billion on co-pay cards and coupons annually.[16] Drug manufacturer Amgen has stated publicly that spending on its co-pay subsidy programs amounts to about *1% of its total product sales*; in the first quarter of 2010, Amgen spent $35 million on co-pay subsidy programs. This amount is likely to increase as more co-pay programs are created and more plan members take advantage of existing programs.

54. Brand-name pharmaceutical manufacturers know that these co-pay subsidy programs work: these programs are now a regular part of life cycle planning for branded drugs, typically launching two to three years before AB-rated generic equivalents of the brand name drug are expected to enter the market. The manufacturer tries to maximize the number of prescriptions written by physicians, filled by members, and paid for by both members and health benefit providers before pharmacies begin automatically substituting the AB-rated generic equivalents for the brand name drug.

55. Health benefit providers have seen significant increases in the number of prescriptions filled for brand name drugs that have co-pay subsidy programs. Recently, co-pay

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[13] *Id.* at 12.

[14] *Id.*

[15] *Id.* at 3, 13-15.

[16] Matthew Herper, *How Bargain Lipitor Could Raise Health Costs*, FORBES.COM, http://blogs.forbes.com/matthewherper/2011/03/16/how-bargain-lipitor-could-raise-health-costs/ (last visited Mar. 2, 2012) (citing Mason Tenaglia, managing director of the Amundsen Group, a consulting firm that has studied the cards). *See also* Visante Study at 6.

subsidy administrators have anecdotally reported that their unnamed clients, manufacturers of branded drugs, earn between a 4:1 and 6:1 return on their investments in these programs.

56. The attack on the prescription drug co-payment system is open and notorious. Large branded drug companies reflexively subsidize co-payments for many brand name drugs simply because they are nearing patent expiry. Co-payment subsidy administration has become a cottage industry. Program administrators boast about the effective and efficient methods by which they have wiped out the personal financial incentives of plan enrollees to select, in consultation with their physicians, less costly medications.

57. Drug companies, including defendant, not only determine the price at which wholesalers or large retailers will purchase prescription drugs from them, but also control the reimbursement benchmark used to determine the amount to be paid for the drugs by public and private health benefit providers. Either by directly determining the so-called average wholesale price (or "AWP") or by determining a related price benchmark known as the wholesale acquisition price (or "WAC") that reporting agencies use to mathematically determine the AWP, branded drug manufacturers cause to be published the widely-used and nearly ubiquitous benchmark prices for payments and reimbursements that health benefit providers make to pharmacies for branded, retail-channel drug products.

58. Branded drug manufacturers, including defendant, know that the reported benchmark that they control, is required to be a reasonably fair estimation of the actual price for the ingredient cost of the drug to the retailer. When a prescription for a privately-insured individual is filled at the retail level (*i.e.*, a pharmacy), the pharmacy charges the member's plan for the ingredient cost of the drug plus a dispensing fee. The amount to be charged for the ingredient cost is based on a percentage discount from the benchmark (*e.g.*, AWP minus 14% for

all branded drugs). Thus, the stated benchmark represents the price that all participants — the health benefit provider, its pharmacy benefit manager, the pharmacy and the manufacturer — understand is a reasonable estimate of the actual cost to the pharmacy on which the payer's reimbursement to the pharmacy is based. Of course, if a cost-sharing provision exists for the member's prescription drug plan, then the cost share (*e.g.*, co-payment or co-insurance) is deducted from the amount owed by the plan to the pharmacy and is imposed on the member as a payment to the pharmacy. However, for subsidized co-pays, the true benchmark is less, resulting in an inflated payment by the health insurers.

59. Routinized co-pay subsidy programs constitute commercial bribery because the programs pay undisclosed kickbacks to plan enrollees to select expensive medications that are paid for by prescription drug benefit providers.

60. Routinized co-pay subsidy programs constitute insurance fraud because routine waiver of co-payments reduces true acquisition costs, yet drug manufacturers withhold co-payment information, do not decrease the applicable reimbursement benchmark for the drugs, and cause inflated payments to be imposed upon private prescription drug benefit providers.

F. Defendant Abbott subsidized health plan members' co-pays for AndroGel and Humira.

61. Defendant designed and implemented the programs described below (collectively, the "co-pay subsidy programs"), relating to the brand name drugs AndroGel and Humira (collectively, the "co-pay subsidy drugs").

62. Each of defendant's co-pay subsidy programs described below alters the carefully calibrated co-payment system negotiated by health benefit providers and their members. Each is intended to steer unsuspecting members toward more expensive brand name drugs when less expensive therapeutic alternatives are available in generic form, with generic price tags.

1. Abbott's AndroGel Restoration Program Savings Card

a. Abbott faced substitution competition from less expensive therapeutic alternatives to AndroGel.

63. On February 28, 2000, the FDA approved AndroGel 1% strength testosterone gel for replacement therapy in men with low testosterone, a condition that affects an estimated 13 million men over the age of 45. On April 29, 2011, the FDA approved a 1.62% strength version of the testosterone gel.

64. Abbott has spent millions of dollars on direct-to-consumer advertising to convince men that they suffer from the condition referred to as "Low T." Over the past five years, U.S. sales of AndroGel have increased annually by double-digit percentages, with U.S. sales approaching $600 million in 2010. Despite these successes, AndroGel and the other leading testosterone gel, Testim, face competition from much less expensive therapeutic alternatives, including injectable testosterone.

b. In the wake of competition from less expensive therapeutic alternatives, Abbott created the AndroGel Restoration Program Savings Card.

65. To combat the competition it was facing from less expensive therapeutic alternatives, in or around early 2008, Abbott created the AndroGel Restoration Program:[17]

[17] http://www.androgel.com/restoration-program/overview.aspx .

Sign up now to pay as little as $10 per month over 1 year for your AndroGel 1.62% prescription and receive valuable support along the way.

66. Prior to September 30, 2011, the program offered an AndroGel Savings Card that paid $20 of a patient's monthly co-pay, for up to twelve uses. Although the program required that refills be accompanied by a separate Savings Card, patients could return to Abbott's website and print a new card each month.

67. Abbott's AndroGel Restoration Program currently advertises that patients can "[p]ay as little as $10 per month." Abbott offers a Savings Card for up to $50 off a patient's monthly co-pay for AndroGel 1.62%, which can be used up to twelve times per patient. Visitors to Abbott's website are encouraged to "[s]ign up now to receive valuable support and up to $600 in savings over 1 year toward your AndroGel 1.62% prescription." The AndroGel Savings Card "is good for one-time use to receive up to $50 in savings after [the] customer pays a $10 out-of-

pocket expense." The offer was originally set to expire on June 1, 2012, but was recently extended until December 31, 2012.

68. Similar information about the AndroGel Restoration Progam is available on Abbott's website for healthcare professionals: www.androgelpro.com.

69. The AndroGel Restoration Program and the AndroGel Savings Card are not need-based programs. They are open to all patients with a prescription for AndroGel, and the Savings Card subsidizes the co-pays of any commercially-insured patients. A patient can sign up for the program and print the Savings Card online by providing his or her name, address, e-mail address, date of birth, and the answers to a few short questions on Abbott's website: https://www.androgel.com/savings/default.aspx?p=form.

70. Abbott advertises its AndroGel savings card in nationally televised commercials, including those touting AndroGel 1.64%.

c. The AndroGel Restoration Program Savings Card specifically provides that it does not apply to Medicare or Medicaid patients or to residents of Massachusetts.

71. Abbott's website outlines the Terms and Conditions governing the use of the AndroGel Restoration Program Savings Card. These Terms and Conditions expressly exclude Medicare or Medicaid patients and residents of Massachusetts:

> TERMS AND CONDITIONS
>
> Offer not valid for prescriptions eligible to be reimbursed, in whole or in part, by Medicare, Medicaid, any other federal or state program, or by private plans or other health or pharmacy benefit programs which reimburse you for the entire cost of your prescription drugs. . . . Offer void in Massachusetts for residents whose prescriptions are covered in whole or in part by third-party insurance, or where otherwise prohibited by law.[18]

[18] http://www.androgel.com/restoration-program/overview.aspx.

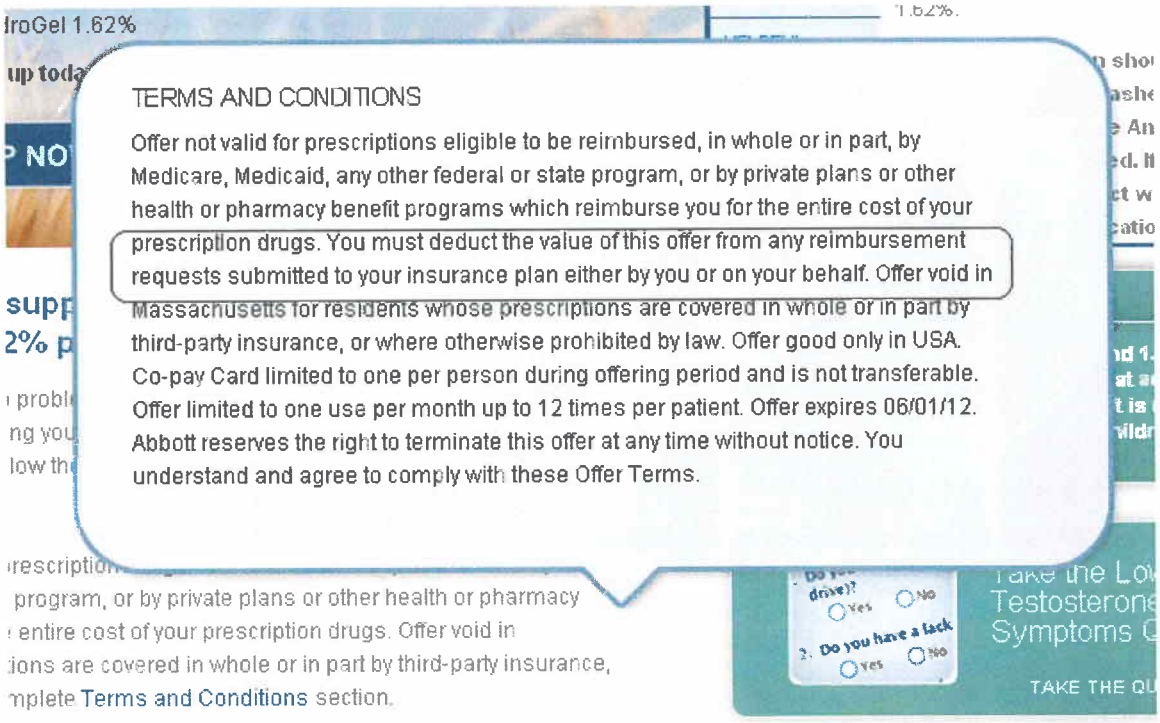
72. If a patient attempts to sign up for the AndroGel Restoration Program with a Massachusetts address, he or she is told: "Since you live in the state of MA, you are not eligible for the Savings Card. You will still receive the educational emails and refill reminders from The Restoration Program."

d. The AndroGel Restoration Program Savings Card functions as an unlawful form of secondary health insurance.

73. The fine print on the AndroGel Restoration Program Savings Card instructs pharmacists to "[d]ispense as prescribed to the patient," and to "[s]ubmit claims using the Group # and Member # listed on this form." Notably, Abbott's co-pay subsidy is processed the same way as a claim for secondary health insurance is processed.

e. Abbott knows that health benefit providers cannot tell when a co-pay is subsidized.

74. Abbott knows that the AndroGel co-pay subsidy program that Abbott and its co-pay savings card administrators have designed makes it impossible for health benefit providers to tell if their members' co-pays are being subsidized by co-pay savings cards. Abbott admits as much in the fine print of the AndroGel Savings Card's Terms and Conditions, where it attempts to push onto patients the responsibility for making such disclosures: "You must deduct the value of this offer from any reimbursement requests submitted to your insurance plan either by you or on your behalf." By burying this disclosure in the fine print of the card's Terms and Conditions, which appear in a pop-up bubble that cannot be printed like other web pages, Abbott makes a weak attempt to shield itself from liability with instructions it knows and intends will not be seen or followed.



2. Abbott's Humira Protection Plan

a. Abbott faced substitution competition from less expensive alternatives to Humira.

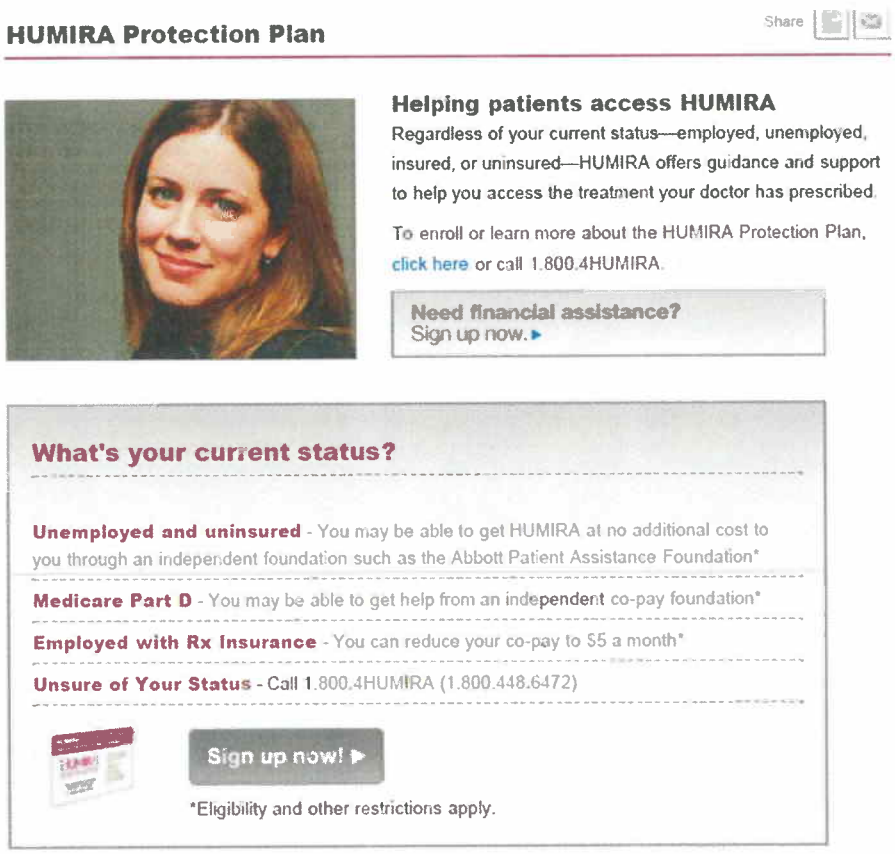
75. On December 31, 2002, the FDA approved Humira (adalimumab) for the treatment of rheumatoid arthritis. On January 18, 2008, Humira was additionally approved for the treatment of moderate to severe chronic plaque psoriasis in adults.

76. Less expensive therapeutic alternatives to Humira include prescription analgesics (acetaminophen and tramadol), prescription NSAIDS (ibuprofen, naproxen), corticosteroids (prednisone), and nonbiologic disease-modifying anti-rheumatic drugs (DMARDS): cyclosporine (Sandimmune, Neoral), azathioprine (Imuran), leflunomide (Arava), methotrexate (Rheumatrex, Trexall), minocycline, sulfasalazine (Azulfidine), and hydroxychloroquine sulfate (Plaquenil).

77. Humira is a very expensive drug, averaging a whopping $1,633 per prescription in 2008.[19] For high-priced branded drugs like these, co-pays matter: As Miles White, Chairman and CEO of Abbott told investors in a 2009 discussion about Humira, "the patient I will tell you is economically very, very sensitive to copays and a $5, $10, $20, $25 copay matters to a patient."[20]

b. In the wake of subsitution competition from less expensive therapeutic alternatives, Abbott created the Humira Protection Plan.

78. To combat the competition it was facing from less expensive brands and generic alternatives, in or around mid-2008, Abbott began offering the Humira Protection Plan:[21]



[19] AARP Board of Directors Chair Bonnie Cramer Testifies Before House Energy and Commerce Subcommittee on Health – Final, FD (Fair Disclosure) Wire (Dec. 8, 2009).

[20] Q1 2009 Abbott Earnings Conference Call – Final, FD (Fair Disclosure) Wire (Apr. 15, 2009).

[21] http://www.humira.com/global/financial-assistance.aspx (last visited Mar. 5, 2012).

79. The Humira Protection Plan covers Humira and the Humira Pen.[22] Abbott tells visitors to its website that if they are "Employed with Rx Insurance – [They] can reduce [their] co-pay to $5 a month."[23]

80. The Humira Protection Plan is not a need-based program. It is open to all patients with a prescription for Humira and subsidizes the co-pays of any commercially-insured patients. Abbott's website invites patients to call 1.800.4HUMIRA to speak to a "myHumira reimbursement counselor" who will help them identify their out-of-pocket costs. Abbott also makes its reimbursement counselors available to call patients' health insurance companies to verify their benefits. Reimbursement counselors can also provide information about co-pay assistance options, including the Humira Protection Plan.

81. A patient need not call to register for the plan, however, as the patient can sign up simply by entering his or her name, address, e-mail address, date of birth and the answers to a few short questions about his or her diagnosis and treatment in an online form available at https://www.humira.com/global/hpp-signup.aspx. Once registration is complete, the patient receives a message stating that a Humira Protection Plan card will be mailed within a week to ten days if the patient meets Abbott's eligibility requirements.

82. The Humira Protection Plan card is advertised directly to patients through full-color advertisements in magazines with nationwide circulation. For example:

- A 2-page color advertisement for Humira targeting patients with psoriasis appeared in the September 13, 2010 issue of People magazine. The advertisement showed a picture of the Humira Protection Plan card administered by OPUS Health and told patients: "With the HUMIRA PROTECTION PLAN your co-pay could be $5 a month."

[22] Humira is supplied as either a single-use, prefilled glass syringe or as a single-use, prefilled pen.

[23] *Id.*

- A similar advertisement appeared in the April 4, 2011 issue of Us Weekly magazine.

- A similar advertisement targeting patients with rheumatoid arthritis appeared in the June 2011 issue of Family Circle magazine.

c. Abbott's Humira Protection Plan specifically provides that it does not apply to Medicare or Medicaid patients, or to residents of Massachusetts.

83. To enroll in the Humira Protection Plan, patients must indicate whether they have insurance, and are prompted to select either "No," "Yes, Private Commercial (e.g., through an employer or former employer)," or "Yes, Federal/Government (e.g., Medicare Part D, Medicaid, VA, Tricare, state program)." Upon information and belief, the patient will be eligible for the program if private insurance is selected, but will be ineligible if Federal/Government insurance is selected.

G. Defendant Abbott hired OPUS Health, TrialCard, and PDMI to administer its co-pay subsidy programs.

84. Abbott depends on cooperation from both pharmacies and program administrators to conduct the co-pay subsidy programs. Defendant compensates both pharmacies and the co-pay benefit administrators for their efforts. Defendant and its co-conspirator administrators process co-pay subsidy claims through a "shadow claims system" that hides the subsidies from health benefit providers.

85. For prescription drugs, plan members present their co-pay cards or coupons along with their health insurance cards (which include the prescription drug plan) at the pharmacy. An individual's primary insurance is processed first, establishing the plan member's co-pay or co-insurance amount[24] and the price of the drug that will be billed to the health benefit provider.

[24] For plan members with a co-insurance responsibility, pharmacists determine the dollar amount to be paid by the member. Sometimes, this amount is referred to, inaccurately, as a "co-pay."

86. The pharmacist then processes the co-pay card or coupon associated with the co-pay subsidy program. The pharmacist enters into the pharmacy computer information on the co-pay card as though it were a form of secondary insurance. The pharmacist notes the amount of the co-pay that will be subsidized by the defendant and conveys that information to a co-pay card program administrator, who reimburses the pharmacy on the defendant's behalf.[25] The plan member pays out-of-pocket the difference between his or her co-payment (or co-insurance) and the amount subsidized by the defendant. The pharmacist then charges the health benefit provider the full amount of the health benefit provider's usual payment for the branded drug in question, *i.e.*, the health benefit provider pays an amount for the co-pay subsidy drug's purchase as if the plan member had made full personal payment of his/her cost sharing obligation.

87. During a transaction *without* the use of the unlawful co-pay subsidy, the pharmacy reports data to the health benefit provider (or its PBM) that enables the provider to know the claim, drug dispensed, amount paid by the plan, amount of co-payment/co-insurance paid, and other data. In a transaction *with* the use of the subsidy, *the information transmitted to the health benefit provider does not include any disclosure that a subsidy was paid*; the plan member's cost-sharing obligation is simply reported to the benefit provider as having been paid.

88. As F. Everett Neville, chief trade relations officer at Express Scripts, one of the country's largest PBMs, told the New York Times in January 2011: "[t]he payer doesn't know, and the P.B.M. doesn't know. . . . We have no ability to stop it and no ability to prohibit it."

89. Here, defendant hired unnamed co-conspirators OPUS Health, Trial Card, and PDMI (collectively, the "administrators") to administer its co-pay subsidy programs.

[25] The administrator pays pharmacies for all co-pay subsidies on the manufacturer's behalf every fourteen to twenty-eight days. The manufacturer repays the administrator on a similar schedule.

1. OPUS Health administers the Humira co-pay subsidy program for Abbott.

90. OPUS Health administers the Humira co-pay subsidy program. OPUS Health is *not* named as a defendant in this action but is an unnamed co-conspirator for purposes of RICO and antitrust violations.

91. OPUS Health advertises that it "pioneered the co-pay assistance space" and that it has "the most extensive industry and product knowledge, providing innovative co-pay assistance, voucher, and patient adherence programs for over 10 years."[26] The company "partners with large and specialty pharmaceutical companies to design and implement industry leading patient co-pay assistance and medication adherence programs" that it claims have "measurable, proven outcomes."[27]

92. According to OPUS Health, it has implemented and managed over 1,000 programs and currently administers over 250 programs for 7 of the top 10 pharmaceutical companies. It boasts that "[o]ver 99.5% of [its] co-pay cards or vouchers are processed flawlessly" at over 60,000 pharmacies in its network, and it claims to be the only co-pay card administrator "that has never had a program refused or turned off" by pharmacy.[28] OPUS Health's pharmacy network includes retail pharmacies in all 50 states, with the greatest concentration in New York, New Jersey, Pennsylvania, Florida and California.

93. Cegedim Relationship Management, OPUS Health's parent company, tells pharmaceutical companies that OPUS Health's co-pay cards "help[ ] level the playing field with

[26] http://www.opushealth.com/manufacturer/programs.aspx (last visited Mar. 5, 2012).

[27] http://www.opushealth.com/manufacturer/who.aspx (last visited Mar. 5, 2012).

[28] http://www.opushealth.com/manufacturer/programs.aspx (last visited Mar. 5, 2012).

other brands and generic products, mitigating the possibility of product substitution at the pharmacy."[29]

94. OPUS Health offers a family of products called "*Smart*Tools" to maximize the effectiveness of its co-pay card programs. These include:

- an online "Specialty Pharmacy Portal" that enables pharmacists to generate "virtual co-pay cards";
- a "Print on Demand" service that allows doctors to print co-pay cards directly;
- a "Pharmacy Direct" system through which a copy of the co-pay card is faxed directly to the pharmacist and attached to the prescription bag that the patient receives when he or she picks up a prescription;
- "Mobil Interactive Messaging" that sends patients text messages reminding them to refill their prescriptions and use their co-pay savings cards;
- "Interactive Pharmacy Outreach" that "allows for targeting and messaging patients in real time based on prescription history," with messages that come from "the trusted 'voice of the pharmacy'"; and
- a "DebitRx®" portal to validate patient eligibility and product information at the point-of-care.[30]

95. On Cegedim Relationship Management's website, OPUS Health provides a series of case studies designed to show prospective customers how its services can (1) increase patient acquisition and market share, (2) overcome managed care reimbursement barriers to increase new brand starts, and (3) increase market share and persistence.

96. In one case study, OPUS Health describes how its savings cards can "bridge the co-pay gap" for brand manufacturers facing "stiff competition."[31] In the case study, co-pay

[29] http://crm.cegedim.com/solutions/usa-marketing/patient-co-pay/OPUS%20Health/Pages/default.aspx (last visited Mar. 5. 2012).

[30] http://crm.cegedim.com/solutions/usa-marketing/patient-co-pay/smart-tools/Pages/default.aspx (last visited Mar. 5, 2012).

[31] http://crm.cegedim.com/solutions/usa-marketing/patient-co-pay/Documents/Incereasing%20Market%20Share%20and%20Persistence.pdf.

reduction cards, which were distributed to patients by their doctors and activated by telephone, offered $10 off a patient's co-pay for three uses. During the four-month test period, OPUS Health reported that 722 patients opted into the program, with 78% redeeming the card and 54% using it two or more times. The drug manufacturer's new brand start share for the product increased by a weighted average of 15.8 share points over the pre-promotion period.

97. On October 17, 2005, a patent application was filed with the U.S. Patent and Trademark Office, listing OPUS Health LLC as assignee and seeking a patent covering a method for processing co-pay subsidy cards.[32]

98. The patent application describes how co-pay cards function just like health insurance cards, and how the co-pay subsidies offered in connection with the cards are processed by the pharmacy just as if they are secondary health insurance:

> ABSTRACT . . . [T]he cards have on them the same indicia as a standard health insurance card, although they are not issued by a health insurance provider. When the card is presented to a pharmacy, the health insurance indicia allows the pharmacy to 'adjudicate' the card, through the standard network, whereby the program administrator will instantly activate the card, if necessary, and provide value to the card, by funding the debit account associated with the card, whereby the card can be used immediately as a standard debit card in payment for the prescription which was filled.
>
> * * *
>
> [0039] . . . [T]he system and method of the present invention have been designed so that the card **10** is treated like an insurance prescription card in that it contains the required data, shown at **24** in FIG. 1. In particular, *as far as the pharmacy computer is aware, the information **24** on the card **10** is treated as yet another insurance card.*[33]

[32] U.S. Patent Application No. 11/252,042 (published Apr. 20, 2006).

[33] *Id.* (emphasis added).

FIG. 1

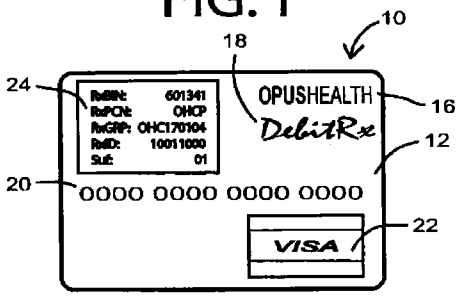
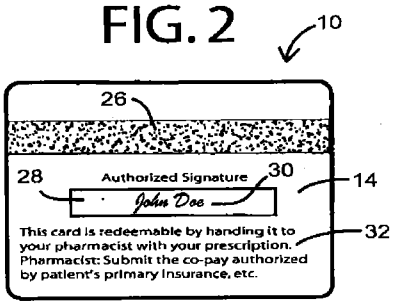


FIG. 2



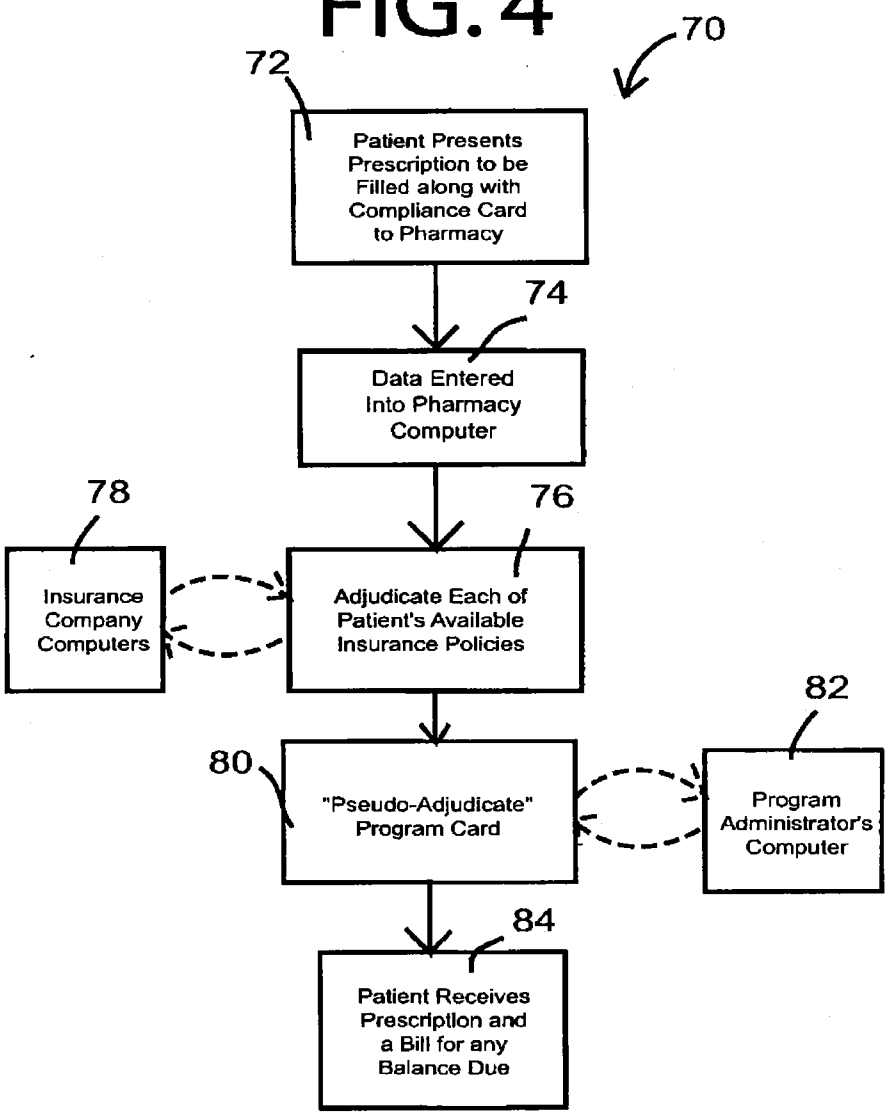
99. The patent application describes how the patient's primary insurance coverage is adjudicated in an electronic transaction that occurs prior to, and is completely separate from, the "pseudo-adjudication" used to process the co-pay card:

> [0038] . . . [T]he networking of pharmacy computers to insurance company or prescription benefit managers' computers conducted over one or more of the networks which provide such service, which currently include WebMD, eRx Networks, and NDC. Thus, it has been standard practice for some time for pharmacy personnel to adjudicate prescriptions by entering the patient insurance identification information, doctor information, and the specific prescription into their computer system, *which then communicates over a network to the insurance company computer*. The result of that communication is that an authorization is provided by the insurance company's computer to the pharmacy confirming the validity of the patient's coverage and authorizing a particular payment to the pharmacy based on such coverage. In that it is not unusual for a patient to have multiple coverage ... *the pharmacy computers are able to communicate with multiple insurance company computers* to obtain verification and funding from the primary company, and then the secondary company, etc., ultimately exhausting the available coverage for the particular prescription and leaving a balance which is then due from the patient as his 'co-pay.'

* * *

[0039] . . . Accordingly, from the perspective of the pharmacy computer system, step **80** is simply handled as one more adjudication in the process, except that *this step **80** is actually a "pseudo-adjudication" is [sic] handled with the program administrator's computer **82**, rather than with one of the insurance company's computers **78**.*[34]

FIG. 4



[34] *Id.* (emphasis added).

2. TrialCard and PDMI co-administer the AndroGel Restoration Program Savings Card for Abbott

100. On information and belief, PDMI and TrialCard co-administer the AndroGel co-pay subsidy program for Abbott. PDMI and TrialCard are not named as defendants in this action but are unnamed co-conspirators for RICO purposes.

101. TrialCard holds certain patents (namely, U.S. Patent Nos. 7,925,531 and 8,055,542) that streamline the processing of co-pay subsidies at the point of sale.

102. PDMI designs, implements, and manages pharmacy benefit programs that align with the business strategies of its clients (*e.g.*, pharmaceutical companies).

103. On information and belief, PDMI has partnered with TrialCard to perform co-pay adjudications, whereby TrialCard's technology is used to initiate the claims process, and claims are then submitted to PDMI under BIN 610020.

a. Trial Card

104. TrialCard advertises that it "provides branded Co-pay card programs that deliver an instant electronic rebate to a patient at the pharmacy, reducing out-of-pocket expense and equalizing tier position for [a manufacturer's] product."[35] The company boasts that its co-pay program "[o]ffsets unfavorable tier/Co-pay position to level [the] playing field for patient out-of-pocket," and that one of its "client[s] reported [a return on investment] exceeding 600%."[36]

105. According to TrialCard, its co-pay subsidy cards are "[a]ccepted at all pharmacies" and are "the most accepted card at the pharmacy in the United States."[37]

106. TrialCard touts that its programs are "innovative, customizable, and reliable," and that it provides "first-to-market solutions" for its clients.[38]

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[35] http://corpsite.trialcard.com/Pages/CoPayPrograms.aspx (last visited Mar. 5, 2012).

[36] *Id.*

[37] *Id.*

107. TrialCard publicizes that it was the "1st to deliver a pharmacy Co-Pay card utilizing the Coordination of Benefit process," and that its co-pay cards provide pharmaceutical manufacturers with the following benefits: 1) "Certainty that [the] co-pay program achieves [the] brand's goal of equalizing formulary co-pays"; 2) the ability "to manage coupon utilization versus depending on sales distribution and pull through"; 3) a "favorable co-pay" for the patient "[r]egardless of Tier position"; and 4) "TrialCard® agents" who "champion and facilitate process for the pharmacy and patient."[39]

108. TrialCard also boasts that it was the "1st to require a real-time patient activation enabling collection of patient level information."[40] Patients who use TrialCard co-pay savings cards "can activate while standing in line versus dealing with a multiple day delay."[41]

109. TrialCard prides itself on being the "1st to allow programs to limit the amount of benefit an individual can receive across multiple offers," which has the benefit of "provid[ing] an annual benefit cap at the patient level" for various co-pay subsidy programs.[42]

110. TrialCard holds a patent, filed on March 15, 2002, for a means of processing co-pay subsidies at the point of sale.[43] This patent describes the processes by which pharmaceutical manufacturers have previously attempted to distribute product samples to patients, and details the inefficiency of these methods:

> One cost-reducing approach that pharmaceutical manufacturers have attempted is the distribution of sample vouchers to prescribing physicians, retail pharmacies, and pharmaceutical sales representatives. With this approach, instead of giving drug product samples directly to patients, physicians give the patients vouchers

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[38] http://corpsite.trialcard.com/Pages/OurInnovations.aspx (last visited Mar. 5, 2012).

[39] *Id.*

[40] *Id.*

[41] *Id.*

[42] *Id.*

[43] U.S. Patent No. 7,925,531 (issued Apr. 12, 2011).

> for the drug product samples. The vouchers may then be redeemed at retail pharmacies for the actual drugs. Alternately, the patients may receive cash or credit rebates at the pharmacies.
>
> Another cost-reducing approach that pharmaceutical manufacturers have attempted is the distribution of product samples via mail order. With this approach, pharmaceutical sales representatives provide prescribing physicians with request authorization forms. Physicians then use the forms to authorize deliveries of product samples directly to the physician's office from third-party pharmaceutical supply warehouses.
>
> These approaches to distributing pharmaceutical product samples have not met with substantial and universal acceptance. All of these approaches lack an effective, efficient and practical system for distributing the trial or sample products to patients and at the same time recording pertinent data, which is easily accessible, relating to prescribing and dispensing the pharmaceutical trial products. [44]

111. To improve efficiency, TrialCard developed an "improved method of dispensing, tracking, and managing pharmaceutical products by communicatively linking prescribers and pharmacies to a central computing station in such a manner that variable values may be provided to different individuals based on selected variables."[45]

112. TrialCard explains how the system can be used to process co-pay subsidy programs:

> For example, the present invention can be useful in dispensing, tracking and generally managing any type of sample or trial product program such as a pharmaceutical sample program. Further, the method and system of the present invention can be used in product loyalty programs, co-pay programs where a third party, such as a pharmaceutical company, participates to make a prescription co-payment for the consumer, patient assistance programs that are sponsored by pharmaceutical companies, and in general is applicable to promoting and advertising goods and services of all types.[46]

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[44] *Id.*

[45] *Id.*

[46] *Id.*

113. On its website, TrialCard explains that its "ground-breaking technology" "enables prescription Co-pay cards and coupons to adjust value based on a patient's insurance coverage. [The] AdjustingValue™ technology maximizes promotional spend for co-pay programs that offer 'Pay No More Than. . .' or 'Save Up To. . .' savings."[47]

114. TrialCard's patent discusses how the co-pay subsidy "media" can be encoded with certain information and can assume the form of a magnetic card that can be read at any pharmacy:

> The product trial media 18 can assume various tangible forms. However, in the example illustrated in FIGS. 2A and 2B and discussed herein, the product trial media 18 is in the form of a conventional magnetic card which again is designed to be compatible with a READ-ONLY magnetic reader terminal located at prescriber and pharmacy sites.[48]

115. These cards help streamline the adjudication process, as a claim can be processed easily after an individual "swipes" his/her card at the pharmacy.

[47] http://corpsite.trialcard.com/Pages/Patents.aspx (last visited Mar. 5, 2012).

[48] *Id.*

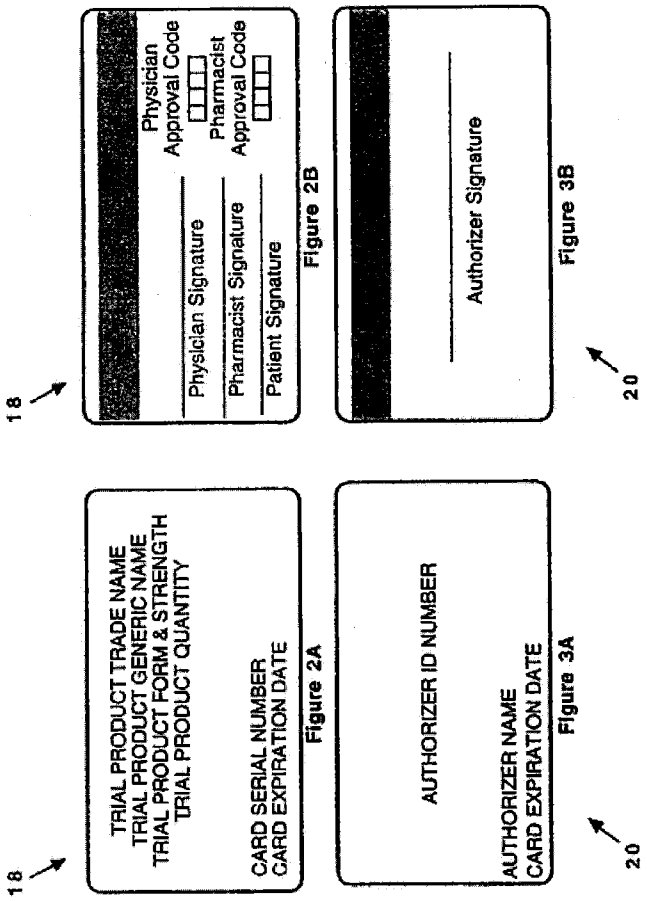

Figure 2 & 3

116. The pharmacist will fill a prescription of any presented media only after undertaking a "validation procedure" to "establish[ ] that the presented media **18** is authentic, still within an acceptable date range, has been activated by a prescriber, and has not previously been validated, or if previously validated, still has valid refills available."[49]

117. TrialCard also holds another patent related to card media, filed on July 21, 2006, which similarly addresses the distribution of pharmaceutical products.[50]

[49] *Id.*

[50] U.S. Patent No. 8,055,542 (issued Nov. 8, 2011).

118. On information and belief, TrialCard submits to PDMI, under BIN 610020, the user information encoded onto the Androgel co-pay savings cards, and PDMI finalizes the adjudication process.

b. PDMI

119. PDMI is a claims administrator with a network that includes over 60,000 pharmacies nationwide, including "most chain pharmacies as well as independent pharmacies."[51] Its pharmacy network agreements cover all aspects of the business it supports, including discount and trial cards. PDMI advertises that it provides a "high level of support" to its clients "in the areas of claims processing and benefit design."[52]

120. PDMI states that it "provides its clients with assistance in benefit plan design based on years of experience processing pharmacy claims. With this knowledge, PDMI has assisted a variety of clients with developing and maintaining their benefits."[53]

121. PDMI has designed co-pay structures to "accommodate all copay requests, including multi-tiered benefits." PDMI can implement "[c]opays based on the greater of a dollar amount or percentage of cost basis[, and it] has the ability to apply minimum or maximum copays. For example, if the percentage copay (the percentage of the drug cost that is the copay) is greater than the maximum amount, the maximum amount will apply. If the percentage copay is less than the minimum amount, the percentage copay will apply. Maximum and minimum amounts can only be fixed dollar amounts."[54]

122. PDMI also provides worksheets detailing how claims should be submitted by pharmacies in accordance with the National Council for Prescription Drug Programs' standards.

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[51] http://www.pdmi.com/pharmacy-network-capabilities.htm (last visited Mar. 5, 2012).

[52] http://www.pdmi.com/benefits.htm (last visited Mar. 5, 2012).

[53] *Id.*

[54] *Id.*

Included on the worksheets are "coordination of benefits" sections, used to establish the order in which health benefit plans pay claims when more than one payor exists.

123. On information and belief, PDMI processes coordination of benefits claims submitted to it by TrialCard and adjudicates them upon receipt.

H. Health benefit providers do not know, and cannot know, when defendant subsidizes their members' co-pays.

124. Health benefit providers are generally aware that drug companies offer co-pay subsidy programs. But health benefit providers do not know, and cannot know, which of the prescriptions that they have paid for have been subsidized. Pharmacists process subsidies as instructed by the defendant and its co-conspirator administrators, and they do not tell health benefit providers or PBMs when a prescription has been subsidized. Defendant, however, possesses detailed records of each and every subsidized prescription. The extent of the injury to Carpenters and the classes can easily be determined through discovery of defendant's co-pay subsidy program records.

I. Defendant's co-pay subsidy programs intentionally interfere with the relationship between health benefit providers and their members.

125. By providing undisclosed kickbacks to reduce or eliminate the cost-sharing mechanism in thousands of health insurance contracts for widely used maintenance prescription drugs, defendant unfairly undermines health benefit providers' best attempts to control prescription drug costs. Pharmacy and Therapeutics ("P&T") committees arrive at formulary placement decisions after considerable decision-making, in an effort to address overall prescription drug costs as a burden on the delivery of quality health care. Even small co-pay subsidies upset the cost share balance so carefully struck by P&T committees in formulary tier structures and cost containment provisions in prescription drug benefit plans. Defendant offers such sweeping bribes that it often effectively reduces the co-pay for branded drugs to *less* than

the average co-pay for therapeutic or AB-rated generic alternatives, thereby completely neutralizing health benefit providers' contractual tiered formulary structure.

126. The co-pay subsidy kickbacks also force other potential short- or long-term changes in available prescription drug coverage. Without a means of enabling cost *sharing* (and make no mistake about it, defendant's co-pay subsidy programs prevent plans and their members from agreeing to effective sharing programs), plans are left to consider wholesale cost *shifting*, under which the benefit provider pays *none* of the cost of a branded drug, and the member pays *all* of the cost, when alternatives to a branded drug exist. At base, defendant has unfairly, deceptively, and improperly interfered with health insurance providers' ability to effectively contract for appropriate cost-sharing provisions in insurance contracts.

127. Finally, as described above, the co-pay subsidy kickbacks are an unlawful form of secondary health insurance.

J. Defendant's co-pay subsidy programs involve misrepresentations sent via mail and the wires.

1. Defendant could not run its programs without using the mail and wires.

128. Defendant makes individuals aware of its respective co-pay subsidy program through the mail and wires. Defendant advertises its co-pay subsidy programs on the Internet, splashing links across websites devoted to its brand name drugs. Defendant advertises its co-pay subsidy programs in magazines and on network television. For example:

- A 2-page color advertisement for Humira targeting patients with psoriasis appeared in the September 13, 2010 issue of People magazine. The advertisement showed a picture of the Humira Protection Plan card administered by OPUS Health and told patients: "With the HUMIRA PROTECTION PLAN your co-pay could be $5 a month."

- A similar advertisement appeared in the April 4, 2011 issue of Us Weekly magazine.

- A similar advertisement targeting patients with rheumatoid arthritis appeared in the June 2011 issue of Family Circle magazine.
- Commercials for AndroGel 1.62% featuring the Savings Card aired nationally in February and March 2012.

129. Defendant has individuals sign up for its programs via the wires. Most patients sign up to participate in the programs online, filling out information that is transmitted to the defendant via the Internet.

130. Defendant sends the physical co-pay cards to individuals, doctors, and pharmacies via the mail.

131. TrialCard envisions activating co-pay cards "via the World Wide Web, calling a toll-free 8xx number, responding with a business reply card, or communicating with the central database through a terminal, such as a magnetic card reader."[55]

132. The co-pay subsidy enterprises do, in fact, use the mail and wires to implement these programs. Defendant and its co-conspirators use the wires to have the pharmacy contact the administrator about the number of subsidized prescriptions filled and the amount subsidized for each prescription, and the administrator in turn contacts the manufacturer and communicates the subsidy information.

133. Defendant also uses the mail and wires to send money to the administrator, and the administrator sends money to the pharmacy to effectuate reconciliation and reimburse the pharmacy for recognizing the co-pay subsidies.

134. These communications between pharmacies, the administrators, and the defendant occur tens of thousands of times per year. Defendant and its co-conspirators possess information about the specific dates of transactions, which defendant has withheld from health benefit plans.

[55] U.S. Patent No. 7,925,531.

2. Defendant conveys two distinct misrepresentations via the mail and wires.

135. Defendant and its co-conspirators make misrepresentations via the wires at the time of the point of sale transaction — that is, when the member presents the co-pay card at the pharmacy — when, as instructed by the defendant, the pharmacist electronically charges the health benefit provider the full benchmark price without accounting for the existence of co-pay subsidies. These transactions necessarily involve the use of the wires.

136. Defendant makes additional misrepresentations via the mail and wires when defendant reports benchmark prices to reporting agencies while failing to account for the routine waiver of co-pays. These transactions necessarily involve the use of the mail and wires.

VI. CLASS ALLEGATIONS

137. Plaintiff Carpenters brings this action pursuant to Federal Rule of Civil Procedure 23, on behalf of itself and two national classes (one for each of the two programs discussed above) defined as:

> All entities in the United States and its territories that are at risk, pursuant to a contract, policy, or plan, to pay or reimburse all or part of the cost of a co-pay subsidy drug prescribed to natural persons covered by such contract, policy, or plan, and who paid for at least one prescription for Androgel or Humira that was subsidized by defendant's co-pay subsidy program(s).

138. The class period runs from when defendant started offering the AndroGel and/or Humira co-pay subsidy programs until defendant stops offering these programs. The precise period will be identified through discovery.

139. Excluded from the classes are (i) defendant, defendant's legal representatives, officers, directors, assignees, predecessors, and successors, (ii) federal and state governmental entities administering prescription drug programs under Medicare, Medicaid, and or other

federally or state-sponsored programs, and (iii) counsel for plaintiff Carpenters and the classes' self-funded health benefit plans (if any).

140. All class members have suffered, and will continue to suffer, harm and damages as a result of defendant's unlawful and wrongful conduct.

141. Defendant's co-pay subsidies are specifically targeted to undermine the cost-share provisions in those contracts.

142. Class members can be precisely determined from defendant's records, the records of the administrators of defendant's co-pay subsidy programs, and pharmacy records. Members of the classes themselves are unable to identify the subsidized prescriptions. However, defendant possesses information about the subsidized prescriptions, including the name and specific identifying information about each participating member and the pharmacy where the prescription was filled. The pharmacy has a record of both the amount of subsidy and the individual's health plan. The administrators also have this information, as well as the accumulated results of the program through all pharmacies. No uninjured parties will be included within the classes because each member can be determined with specificity, based on actual transactional data.

143. The fact of injury or damages to each class member can also be reasonably estimated from existing data. Aggregate damages to the classes as a whole can reasonably be estimated from existing data, and commonly-used mechanisms by which to allocate that award among class members exist.

144. The classes consist of thousands of private health benefit providers. These providers are geographically dispersed throughout the United States. The disposition of all claims in a single action will substantially benefit all parties and the Court.

145. Plaintiff Carpenters is the proposed class representative for each of the classes.

146. The claims of Carpenters are typical of the claims of the classes. Carpenters purchased drugs on behalf of its members whose cost-share obligations were subsidized by defendant. Carpenters, like all class members, paid for too many co-pay subsidy drug prescriptions as a result of defendant's subsidies. Carpenters will fairly and adequately protect the interests of the classes. Carpenters has retained counsel with substantial experience prosecuting nationwide third party payor class actions. Carpenters and its counsel are committed to vigorously prosecuting this action on behalf of the classes and have the financial resources necessary to do so.

147. The factual and legal issues regarding defendant's alleged misconduct are common to all class members and represent a common thread of misconduct resulting in injury to Carpenters and the classes. Common questions of law and fact include:

a. Whether defendant engaged in a course of conduct that improperly increased plaintiff's and other class members' drug costs;

b. Whether defendant engaged in kickback schemes to increase plaintiff's and other class members' drug costs;

c. Whether defendant engaged in a pattern of deceptive and/or fraudulent activity intended to defraud plaintiff and other members of the classes;

d. Whether defendant formed enterprise(s) for the purpose of effectuating its fraudulent schemes;

e. Whether defendant used the U.S. mails and interstate wire facilities and commerce to carry out these fraudulent schemes;

f. Whether defendant engaged in conduct that violated the federal racketeering laws as alleged herein;

g. Whether defendant engaged in conduct that violated federal antitrust laws as alleged herein;

h. Whether plaintiff and the other members of the classes were injured by the conduct of defendant and, if so, the appropriate class-wide measure of damages; and

i. Whether plaintiff and the other members of the classes are entitled to injunctive relief.

148. Prosecution of separate actions by individual class members would create the risk of inconsistent or varying adjudications with respect to individual class members that would establish incompatible standards of conduct for defendant.

149. Defendant has acted on grounds generally applicable to all class members in that defendant's anticompetitive and fraudulent actions uniformly impacted all class members. Accordingly, injunctive relief is necessary to protect all class members from further injury.

150. Plaintiff knows of no difficulty that would prevent this case from being maintained as a class action. A class action is the superior method for fairly and efficiently adjudicating this controversy. The cost of litigating a single action would prevent most class members from bringing suit individually. Class action treatment will, among other things, allow a large number of similarly situated entities to prosecute their common claims in a single forum, thus avoiding the unnecessary duplication of resources that numerous individual actions would require. Moreover, class action treatment allows injured payors, including smaller plans with limited means, to seek redress on claims that might be impracticable to pursue individually.

Thus, absent a class action, there would be no remedy at law for thousands of injured entities. And absent a class action, there would be no mechanism for imposing uniform equitable injunctive relief to the classes as a whole.

VII. CAUSES OF ACTION

COUNTS ONE AND TWO
SUBSTANTIVE RICO VIOLATION
(18 U.S.C. § 1962(c))

151. These Counts allege substantive violations of RICO (as provided in 18 U.S.C. § 1962(c)), relating to the co-pay subsidy programs described above, and is asserted against defendant on behalf of plaintiff Carpenters and the classes.

152. COUNT ONE is asserted against defendant Abbott for the AndroGel co-pay subsidy program. The AndroGel co-pay subsidy enterprise is an association-in-fact comprised of defendant Abbott and unnamed co-conspirators TrialCard and PDMI.

153. COUNT TWO is asserted against defendant Abbott for the Humira co-pay subsidy program. The Humira co-pay subsidy enterprise is an association-in-fact comprised of defendant Abbott and unnamed co-conspirator OPUS Health.

154. These enterprises are referred to collectively as the "co-pay subsidy enterprises." The drugs AndroGel and Humira are referred to collectively as the "subsidized drugs." OPUS Health, TrialCard, and PDMI are referred to collectively as the "administrators."

155. Plaintiff, members of the classes, defendant, and the unnamed co-conspirators are all "persons" as defined by 18 U.S.C. § 1961(3).

A. Defendant and its respective co-conspirators formed association-in-fact RICO enterprises.

156. For purposes of this claim, the RICO co-pay subsidy enterprises alleged herein are associations-in-fact within the meaning of 18 U.S.C. § 1961(4). Defendant and its co-

conspirator administrators, including their directors, employees, and agents, formed association-in-fact enterprises. These co-pay subsidy enterprises are each an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purpose of maximizing sales of subsidized drugs by unlawfully interfering with cost-sharing provisions.

157. Within each co-pay subsidy enterprise there are contractual relationships, financial ties, and continuing coordination activities between defendant and its co-conspirator administrators.

158. On information or belief, members of each co-pay subsidy enterprise have communicated repeatedly over several years to carry out their common purposes, and have entered into, monitored, and enforced contractual and/or agency arrangements regarding payment and the delivery of services. Defendant hired the administrators to carry out the programs.

B. Each co-pay subsidy enterprise engaged in and affected interstate commerce.

159. Each co-pay subsidy enterprise engaged in and affected interstate commerce because it involved thousands of transactions at hundreds of pharmacies all over the country and is attendant to defendant's marketing, distribution, and sale of the subsidized drugs across state boundaries and throughout the United States.

160. During the class period, the illegal conduct and wrongful practices carried out by members of each co-pay subsidy enterprise (including defendant and the administrators) were effectuated by an array of employees, working across state boundaries, who necessarily relied upon frequent transfers of documents and information, products, and funds through the U.S. mails and interstate wire facilities. In particular, administrators transmitted pharmacy data to

defendant, and defendant transmitted funds to the administrators, who transmitted funds to the pharmacies.

C. Defendant associated with its respective co-pay subsidy enterprises.

161. The nature of the co-pay subsidy schemes required defendant to form and participate in enterprises. Defendant hired its co-conspirator administrators and monitored and enforced this contractual arrangement regarding payment and the delivery of services. Each of these actions was necessary to, or helpful in, each co-pay subsidy enterprise's ability to carry out its goal of interfering with plaintiff and class members' cost-sharing provisions and causing plaintiff and class members to be charged an inflated reimbursement rate for subsidized prescriptions.

D. The co-pay subsidy enterprises engaged in a pattern of racketeering activity.

162. Defendant conducted and participated in the affairs of the co-pay subsidy enterprises through a pattern of racketeering activity, including acts that are indictable under 18 U.S.C. § 1341 (mail fraud) and 18 U.S.C. § 1343 (wire fraud).

1. The co-pay subsidy enterprises engaged in schemes to defraud.

163. The co-pay subsidy enterprises engaged in intentional schemes to defraud plaintiff and the classes by interfering with their cost-sharing provisions, causing them to pay for prescriptions of the subsidized drugs that they would not otherwise have paid for, and causing them to pay an inflated rate for each subsidized prescription. These transactions necessarily involve the use of the wires.

164. The co-pay subsidy enterprises engaged in separate but related intentional schemes to defraud plaintiff and the classes by causing misrepresentations to be made via the wires at the time of the point of sale transaction — that is, when the member presents the co-pay card at the pharmacy — when the pharmacist electronically charges the health benefit provider

the full benchmark price without accounting for the existence of co-pay subsidies (as instructed by the defendant). These transactions necessarily involve the use of the wires.

165. The co-pay subsidy enterprises engaged in separate but related intentional schemes to defraud plaintiff and the classes by reporting benchmark prices to reporting agencies while failing to account for the routine waiver of co-pays. These transactions necessarily involve the use of the mail and wires.

166. Defendant knew that entities like plaintiff and members of the classes have cost-sharing programs to reduce the use of brand drugs by their plan members. The purpose and intent of defendant's co-pay subsidy schemes was to overcome such restrictions on brand drug purchases and to cause plaintiff and the classes to pay for an increased number of prescriptions for the subsidized drugs, at artificially inflated prices.

2. The co-pay subsidy enterprises used interstate communications systems to carry out these schemes.

167. The nature of these schemes necessarily required members of each co-pay subsidy enterprise to communicate directly and frequently by the U.S. mails and interstate wire facilities.

168. Many of the precise dates of the co-pay subsidy enterprises' uses of the U.S. mails and interstate wire facilities (and corresponding RICO predicate acts of mail and wire fraud) have been hidden and cannot be alleged without access to defendant's records. An essential part of the successful operation of the co-pay subsidy enterprises was defendant's ability to conceal the use of subsidies from Carpenters and the classes at the point of sale.

169. During the class period, defendant exerted control over the co-pay subsidy enterprises, and in violation of Section 1962(c) of RICO, it conducted and participated in the conducts of the affairs of the co-pay subsidy enterprises, directly or indirectly, in the following ways:

a. Defendant conceived of and implemented the unlawful co-pay subsidy programs;

b. Defendant directly controlled the creation and distribution of marketing, sales, and other materials used to inform patients and physicians about the unlawful co-pay subsidy programs;

c. Defendant set the terms of the programs, including eligibility criteria, amount of subsidy, and number of subsidies;

d. Defendant caused administrators to administer the programs without informing health benefit plans about the subsidies; and

e. Defendant instructed and caused pharmacies to charge health benefit plans an inflated reimbursement rate for subsidized prescriptions by instructing the pharmacy to process the co-pay card as though it were a form of secondary insurance.

170. Defendant's pattern of racketeering likely involved tens of thousands of separate instances of use of the U.S. mails or interstate wire facilities to carry out the unlawful co-pay subsidies. Each of these fraudulent mailings and interstate wire transmissions and/or each transaction to charge health benefit plans an inflated reimbursement rate for subsidized prescriptions constitutes a "racketeering activity" within the meaning of 18 U.S.C. § 1961(1)(B). These violations constitute a "pattern" of racketeering activity within the meaning of 18 U.S.C. § 1961(5) in which defendant intended to defraud Carpenters and members of the classes.

E. The unlawful activity proximately injured plaintiff and the classes.

171. Defendant's participation in the affairs of the co-pay subsidy enterprises, through a pattern of racketeering activity, has directly and proximately caused plaintiff Carpenters and members of the classes to be injured in their business or property. Plaintiff Carpenters, members

of the classes, and others reasonably relied upon a belief that their members were paying their share of prescription drug costs (as determined by the cost-sharing provisions of their particular health plans) and that pharmacies were reporting and charging a reimbursement rate that accurately reflected the price defendant actually charged for the subsidized drugs.

172. Defendant profited directly from the co-pay subsidy schemes in the form of increased sales of the subsidized drugs that plaintiff and the classes would not otherwise have purchased but for defendant's interference with its cost-sharing programs. As a direct and proximate result of defendant's overt acts and/or predicate acts in furtherance of violating 18 U.S.C. § 1962(c), plaintiff Carpenters and the classes have been and are continuing to be injured in their business or property.

173. Plaintiff Carpenters and members of the classes were injured in their property by reason of these violations because plaintiff and members of the classes have paid for an increased number of prescriptions for the subsidized drugs as a result of the co-pay subsidy enterprises' substantive RICO violations. By reason of the unlawful acts engaged in by each co-pay subsidy enterprise, plaintiff Carpenters and the classes have suffered ascertainable loss and damages. These injuries were directly and proximately caused by defendant's racketeering activity.

174. Under § 1964(c) of RICO, defendant is liable to plaintiff Carpenters and members of the classes for three times the damages sustained, plus the cost of bringing suit and reasonable attorneys' fees.

COUNTS THREE AND FOUR
CONSPIRACY TO VIOLATE RICO
(18 U.S.C. § 1962(d))

175. These Counts allege conspiracies to violate RICO (as provided in 18 U.S.C. § 1962(d)), relating to the co-pay subsidy programs described above, and is asserted against defendant on behalf of plaintiff Carpenters and the classes.

176. COUNT THREE is asserted against defendant Abbott for the AndroGel co-pay subsidy program. The AndroGel co-pay subsidy enterprise is an association-in-fact comprised of defendant Abbott and unnamed co-conspirators TrialCard and PDMI.

177. COUNT FOUR is asserted against defendant Abbott for the Humira co-pay subsidy program. The Humira co-pay subsidy enterprise is an association-in-fact comprised of defendant Abbott and unnamed co-conspirator OPUS Health.

178. These enterprises are referred to collectively as the "co-pay subsidy enterprises." The drugs AndroGel and Humira are referred to collectively as the "subsidized drugs." OPUS Health, TrialCard, and PDMI are referred to collectively as the "administrators."

179. Section 1962(d) of RICO provides that it "shall be unlawful for any person to conspire to violate any of the provisions of subsection (a), (b), or (c) of this section." Defendant has violated Section 1962(d) by conspiring to violate 18 U.S.C. § 1962(c). The object of these ongoing conspiracies was to conduct or participate in, directly or indirectly, the conduct of the affairs of the co-pay subsidy enterprises through a pattern of racketeering activity.

180. Defendant adopted the goal of furthering or facilitating the criminal endeavor of the co-pay subsidy enterprises minimally by agreeing to facilitate some of the acts leading to the

substantive offenses, and directly by, as described above, engaging in numerous overt and predicate fraudulent racketeering acts in furtherance of each conspiracy.

181. Defendant not only agreed to the objectives of each 18 U.S.C. § 1962(d) violation of RICO by conspiring to violate 18 U.S.C. § 1962(c), but was aware that its ongoing fraudulent acts have been and are part of an overall pattern of racketeering activity.

182. By hiring administrators to carry out the co-pay subsidy schemes, defendant engaged in overt acts in furtherance of the schemes as well as actual predicate violations of mail or wire fraud. As a direct and proximate result of defendant's overt acts and/or predicate acts in furtherance of violating 18 U.S.C. § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c), plaintiff Carpenters and members of the classes have been and are continuing to be injured in their business or property.

183. Plaintiff Carpenters and members of the classes were injured in their property by reason of these violations in that plaintiff and members of the classes have paid for an increased number of prescriptions for the subsidized drugs as a result of the co-pay subsidy enterprises' conspiracies to violate 18 U.S.C. § 1962(c).

184. By reason of the unlawful acts engaged in by each co-pay subsidy enterprise, plaintiff Carpenters and the classes have suffered ascertainable loss and damages. These injuries were directly and proximately caused by defendant's racketeering activity.

185. By virtue of these violations of 18 U.S.C. § 1962(d), defendant is liable to plaintiff Carpenters and the classes for three times the damages sustained, plus the cost of this suit and reasonable attorneys' fees.

COUNTS FIVE AND SIX
COMMERCIAL BRIBERY IN VIOLATION OF ROBINSON-PATMAN ACT
(15 U.S.C. § 13 (c))

186. These Counts allege commercial bribery in violation of the Robinson-Patman Act (as provided in 15 U.S.C. § 13 (c)), relating to the co-pay subsidy programs described above, and are asserted against Abbott on behalf of plaintiff Carpenters and the classes.

187. COUNT FIVE is asserted against defendant Abbott for the AndroGel co-pay subsidy program.

188. COUNT SIX is asserted against defendant Abbott for the Humira co-pay subsidy program.

189. These programs are referred to collectively as the "co-pay subsidy programs." The drugs AndroGel and Humira are referred to collectively as the "subsidized drugs."

190. Section 2(c) of the Robinson-Patman Act prohibits the payments by drug manufacturers to, or on behalf of, individual insureds to eliminate or reduce their personal obligations under their prescription drug plans' cost-sharing plans. The relevant part of the statute makes it unlawful for any person to:

> (1) pay (or receive)-
>
> (a) anything of value as a commission, brokerage, or other compensation, or
>
> (b) by allowance or discount in lieu of brokerage, *except* for services rendered in connection with a sale or purchase of goods,
>
> (2) when the payment is made to (or by)
>
> (a) the other party to the transaction, or
>
> (b) an agent, representative or other intermediary where the intermediary is
>
> (i) acting for or in behalf of, or

(ii) subject to the direct or indirect control of

(iii) any party to the transaction other than the person by whom the compensation is paid.[56]

191. Generally, these provisions of the Robinson-Patman Act bar commercial bribery, *i.e.*, they prohibit a person from paying off fiduciaries, agents or other intermediaries who control purchasing decisions to be paid for by another. Here, defendant is a "person" making payment of something of value: defendant pays an individual insured to choose a subsidized drug that is paid for by the individual's health benefit provider. Paying individuals who receive prescription drug benefits pursuant to plans offered by private health benefit providers qualifies as a violation of Section 2(c) of the Robinson-Patman Act because the subsidies are "anything of value" which are both (i) paid as "compensation" for purchasing the branded drugs, and (ii) as a "discount in lieu of brokerage."

192. Individual insureds who accept rebates under defendant's co-pay subsidy programs qualify as "agent[s], representative[s] [and] "other intermediar[ies]" because, pursuant to the terms of their agreements with their health benefit providers, they both (i) act on behalf of their health benefit providers in having substantial control in the choice of which medications will be paid for by the health benefit providers and, (ii) under the terms of the agreements with their health benefit providers, act subject to their health benefit providers' direct and indirect control in seeking payment for the selected medications through the terms of their plans. But members do not know these co-pay subsidies are bribes.

193. Defendant offers these co-payment subsidies to privately-insured plan members in order to capture the large payments by private health benefit providers that accompany the relatively modest co-payments made by the individual members. By drastically reducing or

[56] 15 U.S.C. § 13 (c).

eliminating the increased cost-sharing obligation, defendant increases sales of subsidized drugs to the detriment of health benefit plans. Health benefit providers (including Carpenters) invest a great deal of actuarial resources to provide incentives for their members to choose less expensive prescription drug therapy that works as well as pricier drugs. Defendant's co-pay subsidy programs provide illegal inducements to members to choose more expensive drugs, to the detriment of prescription drug plans provided by Carpenters and members of the classes.

194. As a result, defendant's co-pay subsidy programs result in injury to Carpenters and the classes because the payments result in more purchases of subsidized drugs by plaintiff and the classes than would have made purchased absent the illegal inducements.

VIII. DEMAND FOR JUDGMENT

195. WHEREFORE, plaintiff Carpenters, on behalf of itself and the proposed classes, respectfully requests that the Court:

A. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a) and (b)(3), and direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2), be given to the classes, and declare plaintiff Carpenters the class representative for each of the classes;

B. Enter judgment against defendant in favor of Carpenters and the classes;

C. Adjudge and decree the acts alleged herein to be unlawful;

D. Award the classes damages in an amount to be determined at trial;

E. Award the classes threefold damages pursuant to 18 U.S.C. § 1964(c) and 15 U.S.C. § 15(a);

F. Award plaintiff and the classes their costs of suit, including reasonable attorneys' fees as provided by law;

G. Enjoin defendant from offering these or similar co-pay subsidy programs; and

H. Grant such other further relief as is necessary to correct for the anticompetitive market effects caused by defendant's unlawful conduct as the Court deems just.

IX. JURY DEMAND

Pursuant to Fed. Civ. P. 38, plaintiff, on behalf of itself and the proposed classes, demands a trial by jury on all issues so triable.

Dated: March 7, 2012

Respectfully submitted,

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